



• IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

Quarterly Call: Study Managers

- Study & User Support
- Materials Development

Katelyn Benhoff



- Training & User Support

Natalie Dilts



- Lead Application Developer

Bryce Embry



- Study Support
- New Features

Carrie Smith



- Project Director

Emily Serdoz



- Onboarding
- Study & User Support

David Crenshaw



- Onboarding
- Study Support

Bridget Swindell



- System Development
- Study Support

Linda Tan



- Application Developer

Jason Tan



- Application Developer


Evan Wimberly



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7.15.2022 STUDY MANAGERS QUARTERLY CALL AGENDA

- Welcome
- Announcements
- Recent System Updates
- Other feature releases for 2022

About the IREx Quarterly Calls



hear • new • features

- You're busy.
- IREx is busy.
- Call in once a quarter to hear what's new!



learn • new • trends

- Who's using IREx?
- How are folks leveraging IREx on their sIRB studies?



share • your • voice

- Give your opinion
- Ask your questions
- Express your needs

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Announcements

Upcoming Calls

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After today, our calls will combine HRPPs and lead study teams

October 21st, 2022

January 20th, 2022

April 21st, 2023

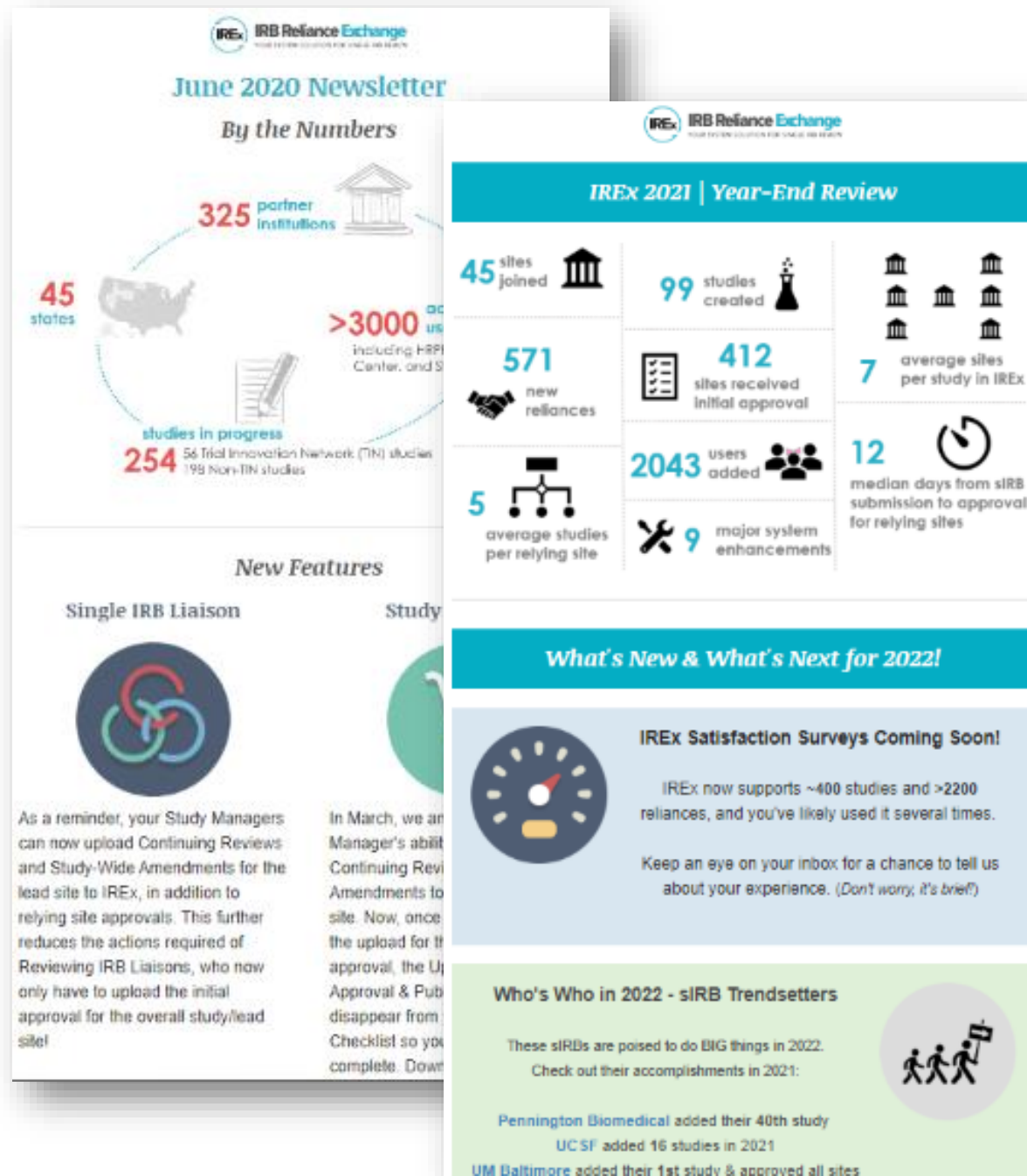
July 21st, 2023

Zoom: <https://zoom.us/meeting/register/tJwud-irrzoIHtKcmf1BEmwhqm7YvXg0rhYq>

The IREx monthly newsletter is coming back!

Check out past issues:

<https://www.irbexchange.org/p/newsletters/>





**Join us Friday, October 21st
1 PM ET/12 CT/11 MT/10 PT**

when the

**SMART IRB Team presents
on the IREx Quarterly Call**

IREx on March 2022 SMART Talk Webinar:

- Intro Slides:
[https://smartirb.org/assets/files/SMART Talk Intro Slides March2022 sIRBInvestigatorPerspective FINAL-ua.pdf](https://smartirb.org/assets/files/SMART_Talk_Intro_Slides_March2022_sIRBInvestigatorPerspective_FINAL-ua.pdf)
- Recording:
<https://player.vimeo.com/video/689280786>



IREx SATISFACTION SURVEYS

- **Respondents**
 - **slRB Liaisons**, after uploading lead site approval
 - **Study managers**, after a few relying sites get approval
 - **PSite HRPPs**, after receiving approval from slRB
- **Satisfaction with using IREx...**
 - on THIS study
 - in general
 - resources
- **Are there features we should improve/add**
- **Participating Site experience**
- ***NEW* Quarterly drawing for \$50 gift card!**
 - **slRB Liaison:** Jennifer Beck, Nationwide Children's Hospital
 - **Participating Site HRPP Liaison:** Lubabah Helwani, University of California, Los Angeles
 - **Study Manager:** Ben Bagwell, Wake Forest University Health Sciences



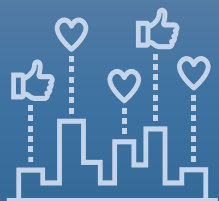
Operational Challenge	IREx Solution	Advantages	Utilization
Documenting reliance & flexible elements of reliance agreement	Study-specific Reliance Plan (SSRP) / SMART IRB Implementation Checklist	<ul style="list-style-type: none"> • Electronic documentation & automated emails • Easily customizable for individual sites • Centralized historical reference 	>2300 reliances
Standardizing “local considerations” questions & processes	Capture static information via the Institutional Profile and study-specific information from the HRPP & PI in the HRP & PI Surveys	<ul style="list-style-type: none"> • Electronic documentation • Collaborative HRPP & PI documentation • Central repository (instead of email) • Facilitative communications 	<ul style="list-style-type: none"> • 291 of 378 IREx studies (79%) capture local considerations • 362 (87%) completed IPs
Supporting sIRB coordination	Empower and equip lead study teams to support sites thru sIRB review and communicate sIRB approvals with sites	<ul style="list-style-type: none"> • Minimize work for the sIRB • Automate site tracking / progress • Automate sIRB approval communications • IREx Admin Support & Training for lead study teams 	<ul style="list-style-type: none"> • >400 lead study team members • Relying site time to approval is improving each year
Capturing sIRB metrics systematically	Capture all timepoints in the sIRB review & approval process	<ul style="list-style-type: none"> • Identify averages / standards • Identify common bottlenecks • Report to policy makers 	<ul style="list-style-type: none"> • Steadily increasing use by new sIRBs each year • Data highlight improvements & ongoing challenges

IREx PUBLICATION

Takeaway: HRPPs and study teams need tools to operationalize the national sIRB mandate – IREx can help!

[Serdoz, E., Edwards, T., Pulley, J., Beadles, J., Ozier, J., Harris, P., . . . Rice, T. \(2022\). The IRB Reliance Exchange \(IREx\): A national web-based platform for operationalizing single IRB review. *Journal of Clinical and Translational Science*, 6\(1\), E39. doi:10.1017/cts.2022.376](#)

IREx Utilization – Quarterly Update



88% of IREx Institutional Profiles are complete (n=377!)



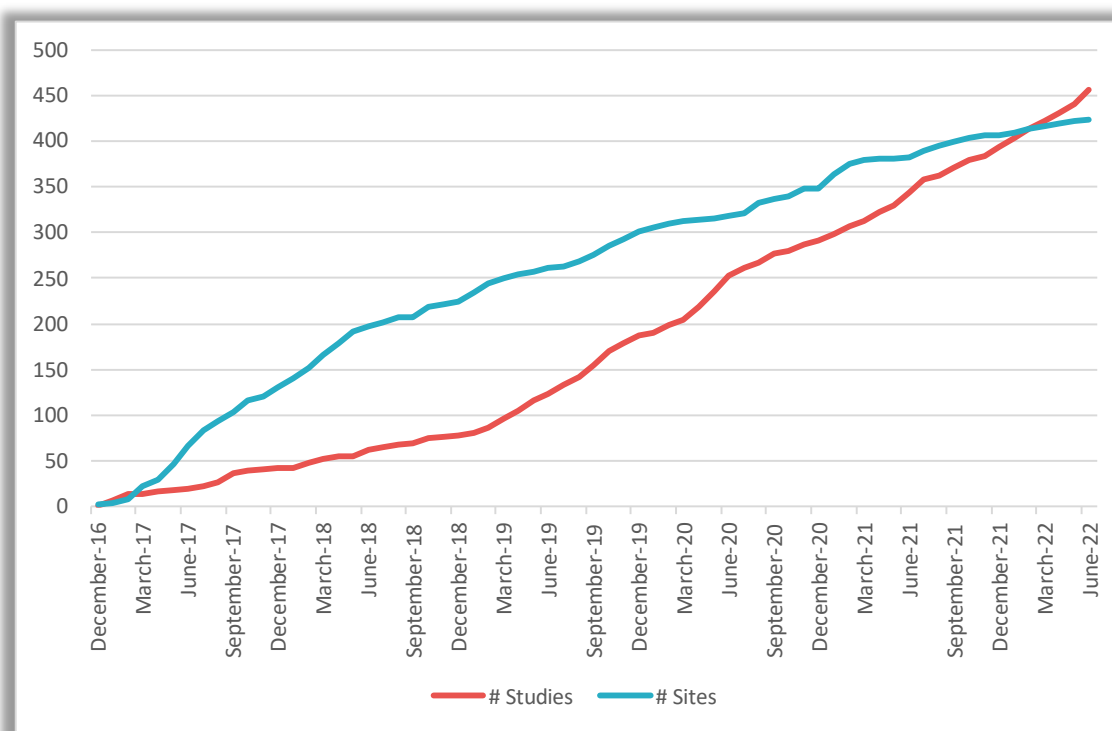
81% of IREx sites have indicated reliance on 1+ studies

- 37 sIRBs using IREx ([view here](#))
- 2602 instances of reliance



89% of ceded sites have sIRB approval in IREx

- 11 days from sIRB submission to approval for PSites
- 17 days for local HRPP review
- 51 days from lead site approval to local HRPP submission



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Recent System Updates

Since January 2022

Complete IREx API for sIRBs



- POST: Study shell to IREx (title, sIRB, sponsor, etc)
- POST: Study initial approval for the lead site (risk categories, review dates, documents, etc.)
- GET: Relying site reliance information and local considerations
- POST: Relying site initial approval (review dates, documents, etc)
- POST: Additional study and site approvals (continuing review, amendments)
- POST: Site and study closures

GOALS

1. Minimize sIRB setup in IREx
2. Streamline ingesting of PSite local reviews
3. Streamline posting of approvals for the life of the study

- Bi-directional API between sIRB's electronic system and IREx
- System agnostic – can connect with any e-IRB system
- General information:
<https://www.irbexchange.org/p/irex-integration-api/>
- Technical information (*IREx login required*):
<https://www.irbexchange.org/s/doc/api>

Relying site approval documents are all listed on a single tab



View As:
Carnegie University

View All Amendments Continuing Reviews

Carnegie University

Protocol Version: 05.02.2021, v3.0

The site has requested a PI change from Dr. John Carr to Dr. Jasmin Divers.

Site Amendment: Full Board #Amend 7, PI Change [change summary](#) (approved 7/8/2021) [Remove Site Amendment](#) **Current**

Continuing Review: Full Board (approved 10/22/2021) **Archived**

Study-Wide Amendment: Full Board #Amend 5, Add Functional MRI (fMRI) [change summary](#) (approved 5/12/2021) **Archived**

Protocol Version: 01.15.2021, v2.0

Study-Wide Amendment: Full Board #Amend 1, Add Cholesterol Panel [change summary](#) (approved 1/22/2021) **Archived**

Protocol Version: 10.29.2020, v1.0

Initial Study: Full Board (approved 11/23/2020) **Archived**

Study Managers can add access for new site coordinators and site PIs



DEMO

VUMC GETTING STARTED

✓ Add P

✓ Add P

✓ Notify

➔ Track Prog Stat

✓ Upload Appro

Participating Project Personnel with Access to IREx

The individuals on this list have access to the study in IREx. As a reminder:
1. **Participating Site Study Teams** get access from their local institution, after their HRPP has accessed the study. This may not occur until the study team has completed a local submission
2. Study team members with access can also give access to other members at their site.

Download CSV

+ Grant Site Coordinator Access

041320: Approvals for Combo Sites (APROPO)

Site	Role	Name	Email
Carnegie University Medical Center	Coordinator	Coordinating Center	irextestingcc@gmail.com
Carnegie University Medical Center	PI	Carnegie PI	irexpi@carnegie.edu
Hartford College of Medicine	PI	PI Hartford	irexpi@hartford.edu
Mellon University Medical Center	PI	PI Hartford	irexpi@hartford.edu
Midwest University Medical Center	PI	Relying Site PI	irextestingpi@gmail.com
Nashville University	PI	Laurie Stanford PI	laurie@stanford.cdu
Stanford University	PI	Laurie Stanford PI	laurie@stanford.cdu
University of Pittsburgh	PI	PITT PI	irexpi@pitt.edu

041320: Approvals for Combo Sites (APROPO)

Study-wide IRB Approvals Approval History Status Summary

View As: Hartford College of Medicine View All Amendments Continuing Reviews

Hartford College of Medicine

Protocol Version: Protocol V3

Study-Wide Amendment: Full Board change summary

Study Info

Key Dates

Change Summary

+ Add Site Amendment
+ Add Site Closure
+ Add Site Coordinator Access

Study Managers can re-send the 'invitation'



Pat King is resending your IREx Study Notification



Serdoz, Emily Sheffer
To: Serdoz, Emily Sheffer

General



Reply



Reply All



Forward



Wed 4/20/2022 10:06 PM

Dear Liaison(s) and Study Investigator,

Apple University (FWA: 99999999) has been listed as a participating site in IREx for the following study:

Title PRIME: Pretend Reliance is Most Excellent

Reviewing IRB Orange University Medical Center

Local Investigator Nev Walsh

What do I do with this email?

Study PI

Many HRPPs require a local submission to initiate the single IRB (sIRB) process at their institution. Reach out to your Human Research Protection Program (HRPP)/IRB Liaisons on this email to find out what you need to do to initiate the sIRB process at your site.

YOU CANNOT ACCESS THE STUDY IN IREX YET.

No action required of HRPP at this point.

This goal of this email is to connect the HRPP and their local study team around next steps for initiating reliance at their site.

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Upcoming Feature Enhancements

Coming in the next few weeks...

Coming soon!

Bridgeton U
GETTING STARTED

- ✓ Register
- ✓ Complete Agreements
- ➔ **Confirm Institutional Profile**
- ➔ **Indicate Reliance**
- ➔ Complete HRP Survey
- 👁 Remind PI To Complete PI Survey
- ✎ Add / Edit Study Team Access
- 🕒 Awaiting Reviewing IRB Approval

Goodall
GETTING STARTED

- ✓ Register
- ✓ Complete Agreements
- ✓ Confirm Institutional Profile
- ✓ Indicate Reliance
- ✓ Complete HRP Survey
- ✓ Review PI Survey (optional)
- ✎ Add / Edit Study Team Access
- 🕒 Awaiting Reviewing IRB Approval

Simplifying Local Considerations Documentation – **RELYING HRPPs**

Relying HRPPs will no longer have to...

1. Upload their site's ICF to the HRP Survey (it is now upload to the PI Survey)
2. Validate the PI Survey (though you can still view & edit it)
3. Add/edit local study team (optional step)



Coming soon!

Carnegie U Med Ctr
GETTING STARTED

➔ Start PI Survey for
Carnegie U Med
Ctr

➔ Awaiting PI Attestation
for Carnegie U Med Ctr

✎ Add/Edit Study Team
Access

GETTING STARTED

✓ Start PI Survey for
Carnegie U Med Ctr ✎

➔ Awaiting PI Attestation
for Carnegie U Med Ctr

✎ Add/Edit Study Team
Access

Simplifying Local Considerations Documentation – **COORDINATORS**

- Coordinators can complete the PI Survey
- PI attestation required
- Edits can be made after PI attestation (requires new attestation)
- Local consent form is attached to PI Survey instead of HRP Survey



Coming soon!

GETTING STARTED

➔ Complete PI Survey

✎ Add / Edit Study Team Access

Carnegie U Med Ctr
GETTING STARTED

✓ Complete PI Survey ✎

✎ Add / Edit Study Team Access

Local PI Survey

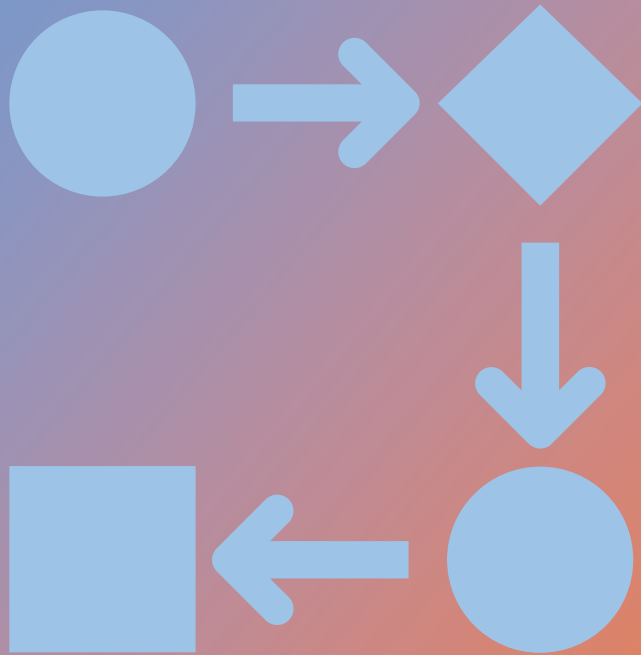
My attestation is a confirmation of the accuracy and completeness of the information provided herein.

Edit and Attest Attest to PI Survey

Study Title	20210908 Asri Main blues clues
Participating Site Name:	Carnegie University Medical Center
STUDY TEAM INFORMATION	
Site Investigator's Name	Carnegie PI
Site Investigator's Email Address	pi@carnegie.cdu
Please review the planned list of personnel who will be engaged in human subjects research. Has all required training for the conduct of the research at your site been completed for each individual, including human subjects protections training, GCP training, and HIPAA training, as applicable?	Yes
Please review the planned list of personnel who will be engaged in human subjects research and indicate whether COI applies:	I have verified there are no financial interests to disclose
SITE-SPECIFIC CONSENT FORMS:	

Simplifying Local Considerations Documentation – INVESTIGATORS

- PI attestation required
- Edits can be made after PI attestation (requires new attestation)
- Local consent form is attached to PI Survey instead of HRP Survey



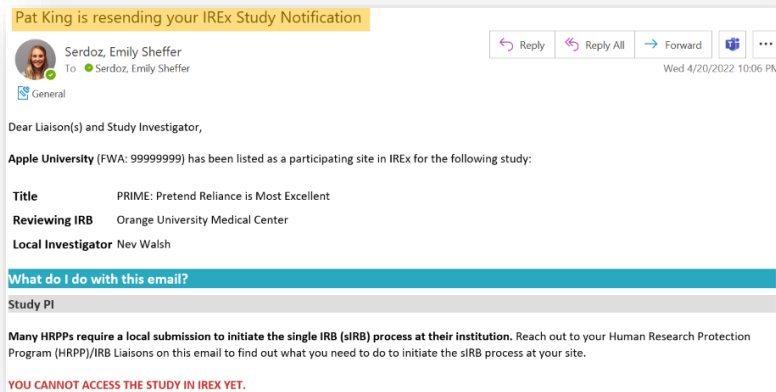
What does this
mean for the
HRPP workflow
when relying
on an sIRB?

New Workflow – Only ONE IREx Log In!



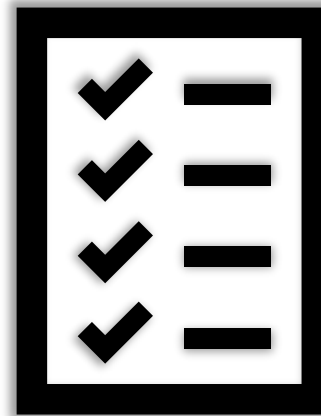
1

Notified of study in IREx



2

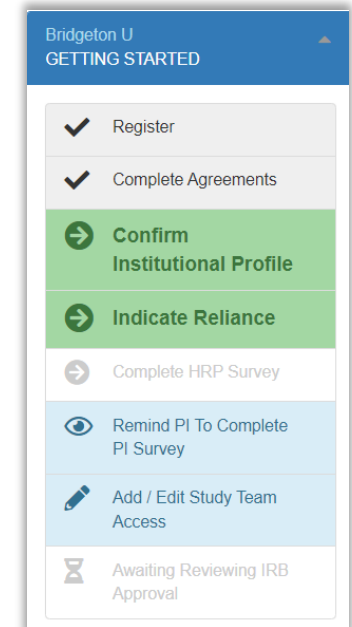
Complete local reviews



Share local reliance process with
study team

3

Login to IREx



- Study team access is granted when HRPP registers
- HRPP notified when PI Survey is completed, if you want to see it

Workflow for HRPPs that prefer to see the PI Survey before it goes to the sIRB



1

Notified of study in IREx

2

Login to IREx

3

Complete local reviews

4

Notified PI Survey completed

5

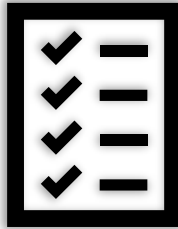
View/edit PI Survey

6

Complete all steps

OPTIONS:

1. Log out after registering
2. Complete steps other than HRP Survey



Dear Relying Site HRPP(s),

Relying Site PI completed the PI Survey for the study below. When you're ready you can finalize the item(s) needing HRPP attention highlighted below for the Reviewing IRB.

Study Title	Study 22
Reviewing IRB	Vanderbilt University Medical Center
Relying Institution	Carnegie University Medical Center
PI Name & Email	Relying Site PI (irextestingpi@gmail.com)
Needs HRPP attention:	Complete HRP Survey
Study Link	https://test.irbexchange.org/feature-branch/public/s/project/3719913

Thank you,
IREx Administrator

GETTING STARTED

- ✓ Register
- ✓ Complete Agreements
- ➔ Confirm Institutional Profile
- ➔ Indicate Reliance
- ➔ Complete HRP Survey
- ✓ Review PI Survey (optional)
- ✎ Add / Edit Study Team Access
- ⌚ Awaiting Reviewing IRB Approval

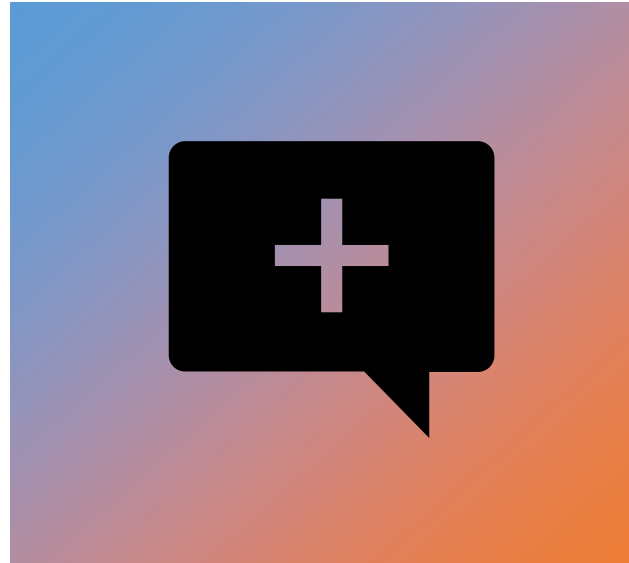
GETTING STARTED

- ✓ Register
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- ✓ Review PI Survey (optional)
- ✎ Add / Edit Study Team Access
- ⌚ Awaiting Reviewing IRB Approval

Share local reliance process with study team

Bridgeton U
GETTING STARTED

- ✓ Register
- ✓ Complete Agreements
- ➔ Confirm Institutional Profile
- ➔ Indicate Reliance
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- 👁 Remind PI To Complete PI Survey
- ✎ Add / Edit Study Team Access
- ⌚ Awaiting Reviewing IRB Approval



Other Enhancements in 2022

Streamline approval uploads by...

- *Allowing study managers to post initial approval for the lead site*
- *Automating approvals of relying sites on study-wide amendments when possible*

Grant PSite study team access to lead site's approvals prior to site registration to...

- *Reduce SM burden of emailing lead site approval to sites*
- *Improve workflow for study teams*
- *Minimize need for Relying HRPP to log into IREx multiple times*

Capture other sIRB communications (e.g., reporting acknowledgments) to...

- *Centralize ALL sIRB communications (not just approvals)*

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Next Call: October 21, 2022

NEW TIME: CALL WILL BE AT 1 PM ET/12 CT/11 MT/10 PT

Zoom: <https://zoom.us/meeting/register/tJwud-irrzoIHtKcmf1BEmwhqm7YvXg0rhYq>